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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,545

Applicant(s)

SAMUELS ET AL.

Examiner

Walter B Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 32-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17 and 32-34, drawn to a balloon catheter cover, classified in class 428, subclass 36.9.
 - II. Claims 18-31 and 35, drawn to a process for making a tubular structure, classified in class 139, subclass 383R.
2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as a process in which the longitudinal yarns are intertwined.
3. During a telephone conversation with Robert B. Stevenson on February 26, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17 and 32-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-31 and 35 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the declaration does not include a claim for domestic priority under 35 U.S.C. 119(e) to provisional application 60/271,770.

Specification

8. The abstract of the disclosure is objected to because the first line is awkward. Furthermore, the abstract discusses the method of making the balloon catheter cover, which has been withdrawn from consideration. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1, 2, 5-7, 9, 10, 14-16 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "a high degree" in claim 1 is a relative term which renders the claim indefinite. The term "high degree" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In regard to claim 2, the term "essentially" is indefinite.

In regard to claims 5 and 6, the phrases "more than two times" and "more than 3 times" are indefinite. More than two or three "times more" than what? The radius? Furthermore, amend the claims so that the amount of "times" is reportly consistently either numerically (2 and 3) or in words (two and three).

Claim 7 recites the limitation "the axis" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim. Amend to "the balloon axis".

In regard to claim 9, insert "is" between "angle ϕ " and "about".

The term "relatively stiff" in claim 10 is a relative term which renders the claim indefinite. The term "relatively stiff" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 14 recites the limitation "the elastomer yarns" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

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Claims 14-16 contain the trademark/trade name Spandex. Where a trademark of trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim 15 recites the limitation "the segmented polyurethanes" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

In further regard to claim 15, is the term "block copolymers" intended to modify both species, or only the second specie?

In regard to claim 16, the term "hard yarn" renders the claim indefinite. The scope of the compositions intended to be recited by this term cannot be ascertained.

In regard to claim 33, the structure intended to be recited by the phrase "changes of the yarn spacing" is indefinite. The structure of the "yarn spacing" must be elucidated, and the structure that results from the "changes" must be recited.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-9, 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al.

In regard to claims 1 and 2, Cook teaches a balloon catheter cover comprising a tubular elastic fabric structure (item 23, Fig. 2) that covers the inner layer (item 22, Fig. 2) of the balloon (item 12, Fig. 2) (col. 2, lines 29-45). Cook teaches that the fabric expands three dimensionally such that an increase in diameter does not require a decrease in length of the balloon and contracts uniformly (col. 3, lines 46-62), and therefore teaches that the tubular elastic fabric structure of the balloon catheter cover has a high degree of stretch and recovery in the circumferential direction. Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns. Fowler et al., however, disclose a tubular elastic fabric structure of interconnected circumferential and longitudinal yarns (col. 3, lines 63-68 and col. 5, lines 30-47 and Fig. 2, 6 and 7). Fowler et al. disclose that the fabric has a uni-directional recovery force in the circumferential direction that results in the structure having a high degree of stretch and recovery in the circumferential direction while having no appreciable elongation at all in the longitudinal direction (col. 1, lines 34-61 and col. 3, lines 63-68). Fowler et al. disclose that the uni-directionality of the fabric is due to the manner in which the circumferential and

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longitudinal yarns are incorporated into the fabric (col. 1, lines 57-61). Therefore, one of ordinary skill in the art would have recognized to have replaced the elastic fabric structure of Cook with the elastic fabric structure of interconnected circumferential and longitudinal yarns of Fowler et al. in order to form a balloon catheter cover that has a unidirectional recovery force which enables the structure to have a high degree of stretch and recovery in the circumferential direction and no appreciable elongation at all in the longitudinal direction as taught by Fowler et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the elastic fabric structure of Cook with the elastic fabric structure of interconnected circumferential and longitudinal yarns of Fowler et al. in order to form a balloon catheter cover that has a unidirectional recovery force which enables the structure to have a high degree of stretch and recovery in the circumferential direction and no appreciable elongation at all in the longitudinal direction as taught by Fowler et al.

In regard to claims 3 and 4, Fowler et al. teach that the circumferential yarns have an elongation at break of more than 300% (col. 4, lines 55-56) and that the longitudinal yarns have an elongation at break of no greater than 50% (col. 4, lines 27-33), a range that falls within the claimed rim of limitations of less than 30%.

In regard to claims 5 and 6, Fowler et al. teach that the degree of stretch in the circumferential direction (the expansion of the radius as taught by Fowler et al.) is greater than 300% (col. 3, line 63-col. 4, line 5 and col. 6, lines 48-56), equivalently greater than 3 times the radius, and therefore also greater than 2 times the radius.

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In regard to claims 7-9, Fowler et al. teach that the longitudinal yarns are positioned at about zero degrees to the balloon axis and the circumferential yarns are positioned at about 90 degrees to the balloon axis (as claimed in claim 9) as clearly shown in Figures 2, 6 and 7, and therefore also at an angle of at least 70 degrees to the balloon axis (as claimed in claim 7) and at an angle greater than 85 degrees to the balloon axis (as claimed in claim 8).

In regard to claims 11-12, Fowler et al. teach that the expansible fabric can be woven, braided, weft knit or warp knit (col. 5, lines 30-33). In regard to claim 11, Fowler et al. teach an elastic tubular woven fabric wherein the circumferential yarns are filling yarns and the longitudinal yarns are warp yarns (col. 8, lines 47-51).

In regard to claim 13, Fowler et al. teach that the fabric is made in a flat form which is subsequently sewed to form the tubular shape (col. 5, lines 36-39). This teaching requires that the edges of the flat fabric are sewn together along the longitudinal direction of the tube as is claimed. Furthermore, the recitation "made by sewing edges of a flat fabric together so as to make a tube having a longitudinal dimension and a circumferential dimension, the edges being sewn together being along the longitudinal dimension" is a process limitation which has not been given patentable weight since the method of forming the balloon catheter cover is not germane to the issue of patentability of the balloon catheter cover itself. The structure of the resultant balloon catheter cover recited by this process limitation, however, has been given patentable weight and has been addressed in the basis for rejection to claim 13 provided above.

In regard to claim 14, Fowler et al. teach that the elastomeric yarn is made from fibers of segmented polyurethane also known as spandex (col. 4, lines 55-60).

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In regard to claim 17, Fowler et al. teach that the longitudinal yarns are made from any conventional yarn, preferably polyester or polyamide (col. 4, lines 48-54).

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al., and in further view of Chaikof et al.

Cook and Fowler et al. teach the catheter balloon cover as discussed above. The circumferential yarns taught by Cook and Fowler et al. are elastomeric braiding yarns, and the longitudinal yarns taught by Cook and Fowler et al. are necessarily relatively stiff axial yarns, since elastomeric yarns are less stiff than nonelastomeric yarns. Fowler et al. teach that the expansible fabric can be woven, braided, weft knit or warp knit (col. 5, lines 30-33). Cook and Fowler et al. fail to explicitly teach that the fabric structure is a triaxial braid. Chaikof et al., however, teach that triaxially braided intraluminal tubular prostheses (col. 3, lines 51-65) that contain reinforcing longitudinal strands prevent the prostheses from contracting longitudinally (col. 8, lines 8-25). Therefore, one of ordinary skill in the art would have recognized to have triaxially braided the fabric since the triaxial braid structure prevents longitudinal contraction of the tubular braided structure as taught by Chaikof et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have triaxially braided the fabric since the triaxial braid structure prevents longitudinal contraction of the tubular braided structure as taught by Chaikof et al.

14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al., and in further view of Gilding et al.

Cook and Fowler et al. teach the catheter balloon cover as discussed above. Fowler et al. teach that the elastomeric yarn is made from fibers of segmented polyurethane also known as

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spandex (col. 4, lines 55-60). Cook and Fowler et al. fail to explicitly teach that the segmented polyurethane of the spandex fiber is selected from the group consisting of polyetherurethaneurea and polyesterurethaneurea block copolymers or combinations thereof. Gilding et al., however, disclose a biomaterial formed from polyether urethane urea block copolymer "spandex" polymers (col. 5, lines 52-68). Therefore, one of ordinary skill in the art would have recognized to have formed the elastomeric yarns from polyether urethane urea block copolymers since polyether urethane urea block copolymers are biocompatible materials as taught by Gilding et al., which would therefore be used as a catheter balloon cover. Furthermore, note that Gilding et al. establish that segmented polyether urethane urea block copolymers are spandex polymers.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al., and in further view of Gilding et al., and in further view of Zafiroglu.

Cook, Fowler et al. and Gilding et al. teach the balloon catheter cover as discussed above. Cook, Fowler et al. and Gilding et al. fail to teach that the spandex fibers are covered with a hard yarn. Zafiroglu, however, disclose that covering an elastic yarn with a hard yarn improves stitching continuity and facilitates the use of very low tensions in the elastic feed yarns (col. 4, lines 41-46). Therefore, one of ordinary skill in the art would have recognized to have covered the spandex yarn of with a hard yarn to improve stitching continuity and facilitate the use of very low tensions in the elastic feed yarns as taught by Zafiroglu.

16. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al., and in further view of Killion et al.

Cook and Fowler et al. teach the catheter balloon cover as discussed above.

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Cook and Fowler et al. fail to explicitly teach that the properties vary along the length of the sleeve as claimed in claim 32, or that the properties vary by changes of the yarn spacing as claimed in claim 33. Killion et al., however, teach an expandable stent that achieves a variation in radial force along the length of the stent by varying stent strut dimensions such as width, length, spacing and overall size (col. 2, lines 66-col. 3, line 27 and Figures 1, 6 and 7). Therefore, one of ordinary skill in the art would have recognized to have varied the yarn spacing along the length of the tubular structure as Killion et al. vary the strut spacing of the stent long the stent in order to provide a tubular structure with expansion properties that vary along the length of the tubular structure as taught by Killion et al.

In regard to claim 34, Cook and Fowler et al. fail to teach that the shape of the balloon catheter cover is not cylindrical. However, Killion et al. teach a stent that is tapered to conform to the interior of a narrowing vessel (col. 4, lines 29-41, col. 5, lines 15-24 and Figures 1 and 6). Therefore, one of ordinary skill in the art would have recognized to have formed the balloon catheter cover in a shape that is not cylindrical in order to form the balloon catheter cover in a tapered shape that would conform to the interior of a narrowing vessel since Killion et al. teach that it is notoriously well known to shape tubular intraluminal devices so that the shape of the device conforms to narrowing vessels.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. 4,834,755 to Silvestrini et al.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Aughenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
03/21/03

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/24/03